

§ 451.3 General reporting requirements.

(a) *Drugs.* Except as noted below, a permittee subject to this Part must notify the permitting authority of the use in a concentrated aquatic animal production facility subject to this Part of any investigational new animal drug (INAD) or any extralabel drug use where such a use may lead to a discharge of the drug to waters of the U.S. Reporting is not required for an INAD or extralabel drug use that has been previously approved by FDA for a different species or disease if the INAD or extralabel use is at or below the approved dosage and involves similar conditions of use.

(1) The permittee must provide a written report to the permitting authority of an INAD's impending use within 7 days of agreeing or signing up to participate in an INAD study. The written report must identify the INAD to be used, method of use, the dosage, and the disease or condition the INAD is intended to treat.

(2) For INADs and extralabel drug uses, the permittee must provide an oral report to the permitting authority as soon as possible, preferably in advance of use, but no later than 7 days after initiating use of that drug. The oral report must identify the drugs used, method of application, and the reason for using that drug.

(3) For INADs and extralabel drug uses, the permittee must provide a written report to the permitting authority within 30 days after initiating use of that drug. The written report must identify the drug used and include: the reason for treatment, date(s) and time(s) of the addition (including duration), method of application; and the amount added.

(b) Failure in, or damage to, the structure of an aquatic animal containment system resulting in an unanticipated material discharge of pollutants to waters of the U.S. In accordance with the following procedures, any permittee subject to this Part must notify the permitting authority when there is a reportable failure.

(1) The permitting authority may specify in the permit what constitutes reportable damage and/or a material discharge of pollutants, based on a con-

sideration of production system type, sensitivity of the receiving waters and other relevant factors.

(2) The permittee must provide an oral report within 24 hours of discovery of any reportable failure or damage that results in a material discharge of pollutants, describing the cause of the failure or damage in the containment system and identifying materials that have been released to the environment as a result of this failure.

(3) The permittee must provide a written report within 7 days of discovery of the failure or damage documenting the cause, the estimated time elapsed until the failure or damage was repaired, an estimate of the material released as a result of the failure or damage, and steps being taken to prevent a recurrence.

(c) In the event a spill of drugs, pesticides or feed occurs that results in a discharge to waters of the U.S., the permittee must provide an oral report of the spill to the permitting authority within 24 hours of its occurrence and a written report within 7 days. The report shall include the identity and quantity of the material spilled.

(d) *Best management practices (BMP) plan.* The permittee subject to this Part must:

(1) Develop and maintain a plan on site describing how the permittee will achieve the requirements of § 451.11(a) through (e) or § 451.21(a) through (h), as applicable.

(2) Make the plan available to the permitting authority upon request.

(3) The permittee subject to this Part must certify in writing to the permitting authority that a BMP plan has been developed.

Subpart A—Flow-Through and Recirculating Systems Subcategory

§ 451.10 Applicability.

This subpart applies to the discharge of pollutants from a concentrated aquatic animal production facility that produces 100,000 pounds or more per year of aquatic animals in a flow-through or recirculating system.